UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 28, 2017

Subject: Efficacy Review for CLB I, EPA Reg. No. 5813-114
(DP Barcode: 441752, E-Submission: 20365)

From: Thao Pham
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Kristen Willis, Acting Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller, Team 32 / Wanda Henson
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: The Clorox Company
c/o PS&RC
PO Box 493
Pleasanton, CA 94566-0803

Formulation from the Label:

Active Ingredient(s)	% by wt.
Sodium hypochlorite	6.05%
Other Ingredients	93.95%
Total	100.00%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): hospital and healthcare disinfectant (bactericidal, virucidal, fungicidal, tuberculocidal), food contact surface sanitizer, non-food contact surface sanitizer, laundry sanitizer, and deodorizer for use on hard, non-porous surfaces

Requested action(s): Removing claim for produce/fruit/vegetable wash, adding ballast water treatment bulletin, and adding additional organisms to the label.

Documents considered in this review:

- Letter from applicant to EPA dated June 14, 2017
- Data Matrix (EPA Form 8570-35)
- 10 efficacy studies (MRID 50289301-50289310)
- Proposed label, RC206041 dated 6/14/17
- Confidential Statement of Formula (EPA Form 8670-4) dated 6/2/2016.

II PROPOSED DIRECTIONS FOR USE

	[Amount [of]] this product	**[Amount [of]] water**	**Instructions**
[For] Disinfecting [& Deodorizing] -or- To Disinfect [& Deodorize] Hard, Nonporous Surfaces			
[To Kill -or- Kills -or- For [99.9% of] [[these] common household germs]:] Insert relevant organism(s) from List 2A	1/2 cup [4 oz]	1 Gal[lon]	[Pre-]wash surface, [mop or] wipe with bleach solution. Let stand -or- Allow solution to contact surface [for] [at least] 5 min[utes]. Rinse well and air dry. -or- To disinfect insert relevant use surface(s) from List 5, pre-wash surface, then mop or wipe with a bleach solution. Allow solution to contact surface for [at least] 5 min[utes]. Rinse well and air dry.

III STUDY SUMMARIES

1.	**MRID**	502893-01	**Study Completion Date:**	2/16/16		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Multi-drug Resistant *Klebsiella pneumoniae* (ATCC 51503)				
Test Method		AOAC Use Dilution Method				
Application Method		Liquid				
Test Substance Preparation	**Name/ID**	CLB, FIS2015.0210 and CLB I, FIS2015.0315				
	Lots ☒ **1** ☐ **2** ☐ **3**	15SSB1				
	Preparation	Tested concentration: LCL Dilution: ½ cup/gallon (1:33) Diluent: 100 ppm AOAC hard water				
Soil load		5% fetal bovine serum				
Carrier type, # per lot		Stainless steel penicylinders, 10				
Test conditions		**Contact time**	4 min 45 sec	**Temp**	20°C	**RH**	52.8%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20004				
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Testing one lot from MRID 50289302 with an increased contact time. Antibiotic sensitivity testing shows multi drug resistance.				

2.	**MRID**	502893-02	**Study Completion Date:**			12/28/15	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Multi-drug Resistant *Klebsiella pneumoniae* (ATCC 51503)					
Test Method		AOAC Use Dilution Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, FIS2015.0210 and CLB I, FIS2015.0315					
	Lots **☐ 1 ☒ 2 ☐ 3**	15SSB1, 15SSB2					
	Preparation	Tested concentration: LCL Dilution: ½ cup/gallon (1:33) Diluent: 100 ppm AOAC hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless steel penicylinders, 10					
Test conditions		**Contact time**	4 min 30 sec	**Temp**	20°C	**RH**	52.1%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19723					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Antibiotic sensitivity testing shows multi drug resistance.					

3.	**MRID**	502893-03	**Study Completion Date:**			2/3/16	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		Vancomycin lntermediate Resistant *Staphylococcus aureus* - VISA (CDC HIP 5836)					
Test Method		AOAC Use Dilution Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, FIS2015.0210 and CLB I, FIS2015.0315					
	Lots **☒ 1 ☐ 2 ☐ 3**	15SSB1					
	Preparation	Tested concentration: LCL Dilution: ½ cup/gallon (1:33) Diluent: 100 ppm AOAC hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless steel penicylinders, 10					
Test conditions		**Contact time**	4 min 45 sec	**Temp**	20°C	**RH**	51.6%
Testing Lab, Lab Study ID		Accuratus Lab Services, A20003					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Testing one lot from MRID 50289304 with an increased contact time. Testing for Vancomycin resistance demonstrates intermediate resistance for vancomycin.					

4.	**MRID**	502893-04	**Study Completion Date:**		12/28/15		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Vancomycin Intermediate Resistant *Staphylococcus aureus* - VISA (CDC HIP 5836)					
Test Method		AOAC Use Dilution Method					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, FIS2015.0210 and CLB I, FIS2015.0315					
	Lots ☐ **1** ☒ **2** ☐ **3**	15SSB1, 15SSB2					
	Preparation	Tested concentration: LCL Dilution: ½ cup/gallon (1:33) Diluent: 100 ppm AOAC hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Stainless steel penicylinders, 10					
Test conditions		**Contact time**	4 min 30 sec	**Temp**	19°C	**RH**	49.2%
Testing Lab, Lab Study ID		Accuratus Lab Services, A19722					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Testing for Vancomycin resistance demonstrates intermediate resistance for vancomycin.					

5.	**MRID**	502893-05	**Study Completion Date:**		8/26/16		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Ebola virus (Zaire-Kikwit) (AIMS# 22955)					
Test Method		Virucidal Efficacy for Use on a Hard, Nonporous Surface					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, FIS2015.0210 and CLB I, FIS2015.0315					
	Lots ☐ **1** ☒ **2** ☐ **3**	15SSB2, 15SSB3					
	Preparation	Tested concentration: LCL Dilution: ½ cup/gallon (1:33) Diluent: 100 ppm AOAC hard water					
Soil load		5% fetal bovine serum					
Carrier type, # per lot		Polysterine petri dish, 1					
Test conditions		**Contact time**	4 min 31 sec	**Temp**	21.3°C	**RH**	
Testing Lab, Lab Study ID		U.S. Army Medical Research Institute of Infectious Diseases, GLP-15-001					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		Tested using EPA approved protocol by U.S. Army Medical Research Institute of Infectious Diseases.					

6.	**MRID**	502893-06	**Study Completion Date:**		3/14/16		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Strain: EMC/2012					
Test Method		Virucidal Efficacy for Use on a Hard, Nonporous Surface					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, FIS2015.0210 and CLB I, FIS2015.0315					
	Lots ☐ **1** ☒ **2** ☐ **3**	15SSB1, 15SSB2					
	Preparation	Tested concentration: LCL Dilution: ½ cup/gallon (1:33) Diluent: 100 ppm AOAC hard water					
Soil load		5% serum					
Carrier type, # per lot		Glass carrier, 1					
Test conditions		**Contact time**	4 min 30 sec	**Temp**	20°C	**RH**	21.9-35.2%
Testing Lab, Lab Study ID		MicroBio Test, 320-608					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		n/a					

7.	**MRID**	502893-07	**Study Completion Date:**		4/6/17		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Enterococcus faecium* (ATCC 6569)					
Test Method		AOAC Disinfectant (Water) for Swimming Pools					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, EPA Reg. No. 5813-111, FIS2015.0212 and CLB I, EPA Reg. No. 5813-114, FIS2015.0320					
	Lots ☒ **1** ☐ **2** ☐ **3**	17SSB02					
	Preparation	Tested concentration: LCL Dilution: 0.50-0.54 ppm available chlorine Diluent: sterile deionized water					
Soil load		n/a					
Carrier type, # per lot		Flask, 3					
Test conditions		**Contact time**	30 seconds	**Temp**	20°C	**RH**	n/a
Testing Lab, Lab Study ID		Accuratus Lab Services, A22651					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		n/a					

8.	**MRID**	502893-08	**Study Completion Date:**			4/18/17	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Enterococcus faecium* (ATCC 6569)					
Test Method		AOAC Disinfectant (Water) for Swimming Pools					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, EPA Reg. No. 5813-111, FIS2015.0212 and CLB I, EPA Reg. No. 5813-114, FIS2015.0320					
	Lots **☒ 1 ☐ 2 ☐ 3**	17SSB01					
	Preparation	Tested concentration: LCL Dilution: 0.50-0.54 ppm available chlorine Diluent: sterile deionized water					
Soil load		n/a					
Carrier type, # per lot		Flask, 3					
Test conditions		**Contact time**	30 seconds	**Temp**	20°C	**RH**	n/a
Testing Lab, Lab Study ID		Accuratus Lab Services, A22935					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		n/a					

9.	**MRID**	502893-09	**Study Completion Date:**			4/12/17	
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Escherichia coli* (ATCC 11229)					
Test Method		AOAC Disinfectant (Water) for Swimming Pools					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, EPA Reg. No. 5813-111, FIS2015.0212 and CLB I, EPA Reg. No. 5813-114, FIS2015.0320					
	Lots **☒ 1 ☐ 2 ☐ 3**	17SSB01					
	Preparation	Tested concentration: LCL Dilution: 0.50-0.54 ppm available chlorine Diluent: sterile deionized water					
Soil load		n/a					
Carrier type, # per lot		Flask, 3					
Test conditions		**Contact time**	30 seconds	**Temp**	20°C	**RH**	n/a
Testing Lab, Lab Study ID		Accuratus Lab Services, A22700					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		n/a					

10.	**MRID**	502893-10	**Study Completion Date:**		4/11/17		
Test organism(s) ☒ **1** ☐ **2** ☐ **3** ☐ **4+**		*Escherichia coli* (ATCC 11229)					
Test Method		AOAC Disinfectant (Water) for Swimming Pools					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	CLB, EPA Reg. No. 5813-111, FIS2015.0212 and CLB I, EPA Reg. No. 5813-114, FIS2015.0320					
	Lots ☒ **1** ☐ **2** ☐ **3**	17SSB02					
	Preparation	Tested concentration: LCL Dilution: 0.50-0.54 ppm available chlorine Diluent: sterile deionized water					
Soil load		n/a					
Carrier type, # per lot		Flask, 3					
Test conditions		**Contact time**	30 sec	**Temp**	20°C	**RH**	n/a
Testing Lab, Lab Study ID		Accuratus Lab Services, A22730					
Reviewer comments (i.e. protocol deviations and amendments, retesting, control failures, neutralizer, etc.)		n/a					

IV STUDY RESULTS

Disinfection – Bactericidal Efficacy

MRID	**Organism**	**No. Exhibiting Growth/ Total No. Tested**		**Average log_{10} CFU/ Carrier**
		Batch 15SSB1	Batch 15SSB2	
4 minute 45 second contact time, 100 ppm AOAC hard water, 5% soil load, ½ cup/gallon				
50289301	Multi-drug Resistant (MDR) *Klebsiella pneumoniae* (ATCC 51503)	0/10	-	5.89
4 minute 30 second contact time, 100 ppm AOAC hard water, 5% soil load, ½ cup/gallon				
50289302	Multi-drug Resistant (MDR) *Klebsiella pneumoniae* (ATCC 51503)	1/10	0/10	6.05
4 minute 45 second contact time, 100 ppm AOAC hard water, 5% soil load, ½ cup/gallon				
50289303	Vancomycin lntermediate Resistant *Staphylococcus aureus* - VISA (CDC HIP 5836)	0/10	-	6.34
4 minute 30 second contact time, 100 ppm AOAC hard water, 5% soil load, ½ cup/gallon				
50289304	Vancomycin lntermediate Resistant *Staphylococcus aureus* - VISA (CDC HIP 5836)	1/10	0/10	6.29

Disinfection – Virucidal Efficacy

MRID No.	**Organism**	**Description**	**Batch**		**Dried Virus Control (PFU/mL)**
			15SSB2	15SSB3	
4-minute 31 second contact time, 100 ppm AOAC hard water, 5% soil load, ½ cup/gallon					
50289305	Ebola virus (Zaire-Kikwit) (AIMS# 22955)	10^{-2} to 10^{-6} dilutions	Complete Inactivation	Complete Inactivation	1.01×10^4
		Plaque Assay Positive Control	6.15×10^4		
		Log Reduction	≥4.00	≥4.00	

Disinfection – Virucidal Efficacy

MRID No.	Organism	Description	Batch		Dried Virus Control (PFU/mL)
			15SSB1	15SSB2	
4-minute 30 second contact time, 100 ppm AOAC hard water, no soil load, ½ cup/gallon					
50289306	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Strain: EMC/2012, BEl Resources	10^{-2} to 10^{-7} dilutions	Complete Inactivation	Complete Inactivation	5.85 $\log_{10}$ ($TCID_{50}$/carrier)
		$\log_{10}$ $TCID_{50}$/carrier	≤1.10	≤1.10	
		Log Reduction	≥4.75	≥4.75	

Disinfection – Swimming Pool Efficacy

MRID No.	Organism	Description	Batch		Dried Virus Control
			17SSB01	17SSB02	
Sterile deionized water, no soil load, 0.50 ppm NaOCl					
50289307	*Enterococcus faecium* (ATCC 6569)	0.5 minutes		0/5	6.85 $\log_{10}$
		1 minute		0/5	
		2 minutes		0/5	
		3 minutes		0/5	
		4 minutes		0/5	
		5 minutes		0/5	
		10 minutes		0/5	
Sterile deionized water, no soil load, 0.51 ppm NaOCl					
50289308	*Enterococcus faecium* (ATCC 6569)	0.5 minutes	0/5		6.78 $\log_{10}$
		1 minute	0/5		
		2 minutes	0/5		
		3 minutes	0/5		
		4 minutes	0/5		
		5 minutes	0/5		
		10 minutes	0/5		
Sterile deionized water, no soil load, 0.48 ppm NaOCl					
50289309	*Escherichia coli* (ATCC 11229)	0.5 minutes	0/5		7.26 $\log_{10}$
		1 minute	0/5		
		2 minutes	0/5		
		3 minutes	0/5		
		4 minutes	0/5		
		5 minutes	0/5		
		10 minutes	0/5		
Sterile deionized water, no soil load, 0.51 ppm NaOCl					
50289310	*Escherichia coli* (ATCC 11229)	0.5 minutes		0/5	7.09 $\log_{10}$
		1 minute		0/5	
		2 minutes		0/5	
		3 minutes		0/5	
		4 minutes		0/5	
		5 minutes		0/5	
		10 minutes		0/5	

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50289301, 50289302, 50289303, 50289304	Disinfectant, bactericidal	Hard, non-porous surfaces	Liquid, ½ cup per gallon of water (1:33 dilution)	4 minutes 45 seconds	5%	100 ppm AOAC hard water	• Multi-drug Resistant (MDR) *Kebsiella pneumoniae* (ATCC 51503) • Vancomycin lntermediate Resistant *Staphylococcus aureus* - VISA (CDC HIP 5836)	**Yes***
50289305, 50289306	Disinfectant, virucidal	Hard, non-porous surfaces	Liquid, ½ cup per gallon of water (1:33 dilution)	4 minutes 30 seconds	5%	100 ppm AOAC hard water	• Ebola virus (Zaire-Kikwit) • Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Strain: EMC/2012	**Yes**
50289307, 50289308, 50289309, 50289310	Disinfectant, bactericidal	Swimming pool water	Liquid, 0.50-0.54 ppm	30 seconds	5%	Sterile deionized water	• *Enterococcus faecium* (ATCC 6569) • *Escherichia coli* (ATCC 11229)	**Yes**

* Note: MRIDs 50289302 and 50289304 each failed one batch for testing at 4 minutes and 30 seconds. Therefore, the minimum contact time supported is 4 minutes and 45 minutes as shown in MRID 50289301 and 50289303.

VI LABEL COMMENTS

Label Date: 6/14/17

1. The proposed label claims that the product, CLB 1, when diluted at 1/2 cup per gallon of water, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 5-minute contact time:

    - Multi-drug Resistant (MDR) *Klebsiella pneumoniae* (ATCC 51503)
    - Vancomycin lntermediate Resistant *Staphylococcus aureus* - VISA (CDC HIP 5836)
    - Ebola virus (Zaire-Kikwit)
    - Middle East Respiratory Syndrome Coronavirus (MERS-CoV), Strain: EMC/2012

    These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, CLB 1 (alternate formulation), when maintained at 0.6-1.0 ppm available chlorine, is an effective disinfectant for swimming pools:

    - *Enterococcus faecium* (ATCC 6569)
    - *Escherichia coli* (ATCC 11229)

    These claims are **acceptable** as they are supported by the submitted data. It should be noted that the product was diluted in sterile deionized water to develop the data submitted to support these claims. Through an agreement with the agency, field testing is waived for this product in support of this claim.

3. The proposed label claims that the product, CLB 1, when diluted at 1/2 cup per gallon of water, is an effective disinfectant against the following on hard, non-porous surfaces in the presence of 5% organic soil for a 5-minute contact time:

    - Multi-drug Resistant *Acinetobacter baumannii*
    - Avian influenza [Type A] virus (H5N1)
    - Avian Influenza A (H7N9) virus
    - Coxsackievirus B3 virus
    - Mumps virus

    These claims are **acceptable** as they are supported by data submitted for EPA Reg. No. 5813-111.

4. Throughout the label, revise units from ounces to fluid ounces.

5. On page 9, 12, and 15 of the label, for mold and mildew removal, the claims for effectiveness at ¾ cup per ¾ gallon at 5 minutes is supported by data submitted for EPA Reg. No. 5813-100.

6. On page 14 of the label, remove "to prevent the spread of Cold & Flu Viruses" or revise "prevent" to "reduce" and add the qualifier "on treated surfaces."

7. On page 17 of the label, next to Influenza A virus, remove "flu virus." Next to Adenovirus [type 2], revise "causes colds" to "a cause of the common cold." Next to Rhinovirus type 37, revise to "[(a cause of the common cold)]."

8. On page 20 of the label, further clarify “stainless” (e.g. stainless steel).

9. On page 21-22 of the label:
    a. Qualify bullets that combine cleaning and disinfection claims with “when used according to disinfection instructions”
    b. Remove claims to “protect” areas or surfaces.
    c. Remove claim to “prevent the spread of cold and flu viruses”.
    d. Remove or revise “meets AOAC efficacy standards” to “tested using the AOAC Use Dilution Method.”

10. On page 23 of the label, insert the table of relevant viruses to support each virus type under “Emerging Viral Pathogen Claims” from the Terms of Registration letter.

11. On pages 24-27
    a. Clarify claims to “protect surfaces” to be specific for non-public health (e.g. stains or odor)
    b. Clarify claims for “surface attackers” or “destroyers” to be specific for non-public health cleaning only
    c. Qualify “around the home” with either “hard nonporous surfaces” or specify that the claim is only for non-public health cleaning.

12. On page 44 of the label, remove claims for “rubber teat cups and tubes.” Data only supports use on hard, non-porous surfaces.

Notes to PM:

- Please verify language regarding use in septic and waste water treatment.
- Please verify Ballast Water Treatment Bulletin.
- No efficacy data is available to support meat and poultry processing water use.